



Eczema?



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Overview

Are you one of the millions of Americans suffering from eczema?

Teres Bio™ is introducing a new clinical research study that may provide an alternate treatment option.

Atopic dermatitis (eczema) is a common skin condition that affects 7-10% of adults in the US as well as 10-20% of children. Currently there is no cure. While there are medications available to treat symptoms, many people still struggle to achieve symptom relief.

This is a clinical research study to investigate the safety and efficacy of a new topical ointment as a potential treatment for those struggling with atopic dermatitis.

The purpose of the Ter-101 Study is to evaluate the safety and effectiveness of an investigational medicated ointment for mild or moderate atopic dermatitis in patients aged 12-65.

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Eczema

What is Eczema?

Atopic dermatitis (AD) is a chronic, recurrent form of eczema that is characterized by itching, redness, and skin dryness. Most commonly, AD affects the cheeks, neck, hands, arms, and legs.



In people with AD, the skin immune system becomes overactive. Patients have skin inflammation, changes in the skin barrier, itching and rashes that may appear purple or brown in darker skin tones. When AD flares up symptoms worsen, which can lead to intense itching, sores and skin thickening.



Details

Trial Details



This study has a 1:1 randomization design. That means you have a 50/50 chance of either receiving the study ointment or a vehicle (placebo). The vehicle (placebo) is an ointment that doesn't have any active medical ingredients.



The investigational topical ointment or vehicle (placebo) will be applied twice a day to areas of the skin affected by atopic dermatitis twice daily for four weeks.



This study will be conducted under the supervision of a licensed doctor. Participation is voluntary, and you have the option to stop at any time.

You and the doctor will not know the treatment assignment (investigational ointment or placebo) until the end of the study. However, in case of an emergency the doctor can quickly find out.

Eligibility

Eligibility Requirements

An eligible participant for this study must be:

- ✓ 12-65 years old
- ✓ Have mild or moderate AD
- ✓ Have a diagnosis of atopic dermatitis for at least 6 months
- ✓ NOT currently pregnant or expecting to become pregnant
- ✓ Able and willing to consent*

Additional eligibility criteria will be assessed by the study doctor or staff during the screening process prior to being enrolled in the study and receiving any investigational medication. Not all individuals will qualify to participate.

* For anyone between the ages of 12-17, a parent or guardian needs to provide consent.

Participation

What does participation look like?

Participation in the study will last between 5-9 weeks and consists of three parts:

- ✓ If interested and you qualify for the study, you will be asked to review and sign a consent form along with the study doctor overseeing the study. Once signed you will officially enter a screening period.
- ✓ During a screening period of up to 35 days, the study doctor will perform tests and procedures to determine if you or your child is eligible to participate and you will need to stop other medications that treat your eczema.
- ✓ If eligible, you or your child will be randomly assigned to receive either the investigational medication or a placebo (which contains no active medication). The investigational medication and the placebo are both topical ointments. You or your child will apply the treatment twice daily for 4 weeks. You will record your itch and your study drug applications every day. The study doctor will explain all study requirements, procedures and length of participation in greater detail during the screening period.

Benefits

Benefits of Participating

Atopic dermatitis is a common condition that can be difficult to control, and can have a negative impact on quality of life.

Some potential benefits from participating:

- ✓ A possible new treatment option for yourself.
- ✓ The information and knowledge gained from this study could help others suffering from atopic dermatitis in the future.
- ✓ All study related procedures will be provided to you at no cost.

Participation is 100% optional and the clinical research study team will discuss all benefits and risks with you in more detail.

More information

For more information, please visit:

trials.spark.com/trial/eczema

